



Medical Necessity Criteria for Attention Deficit Hyperactivity Disorder (ADHD) Agents

Background

Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy Agents. This drug class includes agents primarily used to treat ADHD, some of which have FDA indications for narcolepsy, as well as three agents that are indicated for the treatment of narcolepsy, but not ADHD. After evaluating the relative clinical and cost effectiveness of the ADHD and narcolepsy agents, the DoD P&T Committee recommended that the following medications be designated as non-formulary. All of these medications are primarily used for ADHD. This recommendation has been approved by the Director, TMA.

Effective Date: 18 April 2007

- Daytrana (methylphenidate patch)
- Focalin (dexmethylphenidate immediate release)
- Focalin XR (dexmethylphenidate immediate release)

Effective Date: 16 April 2008

- Daytrana (methylphenidate patch)

Patients currently using a nonformulary Attention Deficit Hyperactivity Disorder (ADHD) Agent may wish to ask their doctor to consider a formulary alternative.

Special Notes:

1. Active duty cost share always \$0 in all points of service for all three tiers; Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.
3. ADHD agents may be divided into two general groups: 1) stimulants (which include both amphetamine products such as Adderall XR and Vyvanse, and methylphenidate products such as Concerta, Metadate CD, and Ritalin LA) and 2) the non-stimulant atomoxetine (Strattera). Extended release formulations of the stimulants are most commonly used, with immediate release formulations reserved for dose titration or for augmenting treatment during specific time periods. In most cases, Focalin (dexmethylphenidate immediate release) would not be used as a sole therapy; therefore, medical necessity review is based on extended release products only. Strattera is less commonly used than the stimulants and is often reserved for specific patient groups (e.g., patients who cannot tolerate the adverse effects of stimulants).
4. Accordingly, therapeutic alternatives to dexmethylphenidate (Focalin, Focalin XR), methylphenidate patch (Daytrana), and lisdexamfetamine (Vyvanse) are considered to be the formulary extended release stimulant products: extended release methylphenidate (e.g., Concerta, Metadate CD, Ritalin LA) and extended release mixed amphetamine salts, (Adderall XR).

Medical Necessity Criteria for Attention Deficit Hyperactivity Disorder (ADHD) Agents

All current and new users of nonformulary ADHD agents must meet one of the following criteria in order for medical necessity to be approved:

1. Use of ALL of the following formulary alternatives is contraindicated (e.g., due to hypersensitivity): extended release methylphenidate (e.g., Concerta, Metadate CD, and Ritalin LA) and extended release mixed amphetamine salts (Adderall XR).
2. The patient has experienced or is likely to experience significant adverse effects from ALL of the following formulary alternatives: extended release methylphenidate (e.g., Concerta, Metadate CD, and Ritalin LA) and extended release mixed amphetamine salts (Adderall XR).
3. Use of ALL of the following formulary alternatives has resulted in therapeutic failure: extended release methylphenidate (e.g., Concerta, Metadate CD, and Ritalin LA) and extended release mixed amphetamine salts (Adderall XR).
4. **(Daytrana patch only)** - The patient is unable to take oral medications.

Medical necessity criteria for Daytrana, Focalin, and Focalin XR recommended by the DoD Pharmacy & Therapeutics Committee at the Nov 2006 meeting & approved by the Director, TMA on 17 Jan 2007. Medical necessity criteria for Vyvanse recommended by the DoD Pharmacy & Therapeutics Committee at the Nov 2007 meeting & approved by the Director, TMA on 13 February 2008. For more information, please see the [DoD P&T Committee minutes](#).

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TRICARE Pharmacy Program Medical Necessity Form for Daytrana, Focalin, Focalin XR



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This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- Formulary medications for Attention-Deficit / Hyperactivity Disorder (ADHD) include Adderall immediate-release and Adderall XR and generics, Concerta and generics, Metadate CD, Ritalin LA, Strattera, immediate/sustained release methylphenidate, dextroamphetamine, and methamphetamine. Daytrana (methylphenidate patch), Focalin (immediate release dexamethylphenidate), Focalin XR (extended release dexamethylphenidate), and Vyvanse (lisdexamfetamine) are non-formulary, but available to most beneficiaries at the non-formulary cost share. NOTE: This form applies to Daytrana, Focalin, and Focalin XR. A separate form applies to Vyvanse.
- You do NOT need to complete this form in order for non-active duty beneficiaries (spouses, dependents, and retirees) to obtain Daytrana, Focalin, or Focalin XR at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary medication instead of a formulary medication is medically necessary. If Daytrana, Focalin, or Focalin XR is determined to be medically necessary, non-active duty beneficiaries may obtain it at the formulary cost share.
- TRICARE will not cover a non-formulary medication for Active duty service members unless it is determined to be medically necessary instead of a formulary medication. If a non-formulary medication is determined to be medically necessary, it will be available to Active duty service members at no cost share.

MAIL ORDER and RETAIL	<ul style="list-style-type: none">The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to: TpharmPA@express-scripts.com	MTF	<ul style="list-style-type: none">Non-formulary medications are available at MTFs only if both of the following are met:<ul style="list-style-type: none">The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF.The non-formulary medication is determined to be medically necessary.Please contact your local MTF for more information. There are no cost shares at MTFs.
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Step 1 Please complete patient and physician information (Please print)

Patient Name:	Physician Name:
Address:	Address:
Sponsor ID #	Phone #:
Date of Birth:	Secure Fax #:

Step 2 Non-formulary medication requested:

- ☐ Dexmethylphenidate products (Focalin, Focalin XR)
☐ Methylphenidate patch (Daytrana)

Please explain why the patient cannot be treated with the formulary medications. Circle a reason code if applicable. You MUST supply a specific written clinical explanation as to why each of the formulary medications would be unacceptable.

Formulary Alternative	Reason	Clinical Explanation
Extended release methylphenidate (e.g., Concerta, Metadate CD, Ritalin LA)	1 2 3 4	
Extended release mixed amphetamine salts (Adderall XR)	1 2 3 4	

Note: The formulary alternatives listed above only include the extended release stimulant products. In most cases, Focalin (dexmethylphenidate immediate release) would be used for dose titration or to supplement the use of Focalin XR, not as a sole therapy; therefore, medical necessity review is based on the extended release stimulant products. Approved medical necessity determinations for dexmethylphenidate products will apply to both Focalin and Focalin XR.

Acceptable clinical reasons for not using a formulary alternative are:

- Use of the formulary alternative is contraindicated (e.g., due to hypersensitivity).
- The patient has experienced or is likely to experience significant adverse effects from the formulary alternative.
- Use of the formulary alternative has resulted in therapeutic failure.
- Daytrana patch only – the patient is unable to take oral medications.

Step 3 I certify the above is true to the best of my knowledge. Please sign and date:

Prescriber Signature	Date
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